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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/222,123 12/29/98 RAY

R 6328-21

EXAMINER

IM31/0509

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ART UNIT

PAPER NUMBER

1743

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/222,123

Applicant(s)

Ray et al

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-12 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2001 has been entered. Claims 1-12 and 19-26 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 7, 8, 10, 19, 21, 22 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,609,160 to Bahl et al (hereinafter Bahl et al >160).

Bahl et al '160 teach a fluid sample collection device comprising a plastic frame having a handle end (30, 40) and a collection end. The device contains an absorbent cotton (cellulosic) pad (50) for collecting the sample. There are openings (32, 42)

dep +
make 103

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through the collection end of the device such that the absorbent pad is exposed and capable of collecting the sample. The device also contains an additional opening⁴⁸(28) which allows the oral sample to be extracted during centrifugation. At col. 4, lines 8-14, Bahl et al '160 disclose that a portion of the absorbent pad is treated with a chemical indicator (dye) such that when sufficient fluid is taken up by the pad, a change in color occurs. Also provided are a package for return of the sample by mail, and an identification card (90) containing information for identifying the sample. See figures 1 and 10.

It is noted that Bahl et al '160 does not explicitly teach that the apertures "facilitate removal of a portion of the collection pad", however, Applicants' define the means for performing this function as apertures through the collection end of the device. MPEP 2114 states that "means plus function limitations are met by structures which are equivalent to the corresponding structures recited in the specification", citing *In re Ruskin*, 347 F.2d 843, 146 USPQ 211 (CCPA 1965).

It is also noted that "drying the sample" is not disclosed by Bahl et al '160, however, this is Applicants' intended use which is accorded no patentable weight since the claims are directed to a device which is defined by its structure and not function. See MPEP 2114.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated within the meaning of 35 U.S.C. 102b in view of the teachings of Bahl et al '160.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 5, 11, 12, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al '160 and further in view of US patent 6,165,416 to Chandler (hereinafter referred to as Chandler '416).

With respect to the above mentioned claims, Applicants claim that the device uses glass fiber as an absorbent material and has a plurality of collection pads and apertures.

Chandler '416 teaches a sample collection device comprising an elongated dipstick collection member having an absorbent matrix. The absorbent matrix is disclosed as being any of the conventional absorbent materials including cellulose, nitrocellulose, glass fiber and sintered fiber (col. 3, lines 58-65). Since such materials are well known in the art, it would have been obvious to one of ordinary skill in the art to use any of the materials in the collection device of Bahl et al '160.

With respect to the device containing a plurality of apertures and collection pads, it would have been obvious to one of ordinary skill in the art to incorporate multiple apertures and collection pads so that multiples tests or assays may be performed on a single support.

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Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 U.S.C. 103 in view of the teachings of Bahl et al '160 and Chandler '416.

6. Claims 2, 3, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al '160, and further in view of US Patent 5,656,503 to May et al (hereinafter May et al '503).

With respect to the above mentioned claims, Applicants' invention is directed to the collection pad containing urine and albumin. Applicants' invention is further directed to the use of polyvinyl alcohol as the absorbent material.

May et al '503 teaches a test device for detecting analytes in biological samples, such as urine, comprising a hollow casing containing a porous carrier and a bibulous receiving member. At col. 9, lines 45-48, May et al '503 teaches the use of blocking reagents such as BSA (albumin) and polyvinyl alcohol for blocking excess binding sites in each zone of the test device.

Thus, it would have been obvious to one of ordinary skill in the art to incorporate such reagents into the device of Bahl et al '160 where the blocking of such binding sites is necessary.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Bahl et al '160 and May et al '503

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Response to Arguments

7. The following is in response to Applicants' remarks filed on January 26, 2001:

Applicants' argue that the Bahl et al '160 reference fails to teach 1) drying of the liquid sample; 2) means for facilitating removal of a portion of the collection pad; 3) an information card; 4) a collection pad pretreated with a chemical.

Regarding "drying of the sample", this is one of Applicant's intended uses for the collection device, which is not accorded patentable weight. MPEP 2115 states that "apparatus claims must be structurally distinguishable from the prior art" and that "apparatus claims cover what a device is, not what a device does". Thus, drying of the sample does not make the instant claims patentably distinct from Bahl et al '160.

With respect to Applicants' assertion that Bahl et al '160 fails to teach "means for facilitating removal of a portion of the collection pad", Bahl et al '160 clearly teaches an aperture which Applicants describes in the specification as the structure which carries out their recited means. MPEP 2181 states "the means or step plus function limitation should be interpreted in a manner consistent with the specification disclosure. If the specification defines what is meant by the limitation for the purposes of the claimed invention, the examiner should interpret the limitation as having that meaning". Thus, Applicants' recitation of "means for facilitating removal of a portion of the collection pad" is not patentably distinct from Bahl et al '160 since the reference teaches an aperture which is **structurally capable of functioning** in such a manner.

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With respect to Applicants' assertion that Bahl et al '160 fails to teach an information card "for providing information about the patient", this recitation is Applicants' intended use of the information card. Bahl et al '160 clearly teaches a card containing information. Applicants' mere use of patient information on the card, as opposed to identification information, is not a patentable distinction. It is well within the knowledge of the skilled artisan to include any kind of information on testing devices, including patient information, product information, identification information, instructions, etc.

Lastly, Applicants state that Bahl et al '160 fails to teach that the collection pad is pretreated with a chemical. Applicants' statement is incorrect as at col. 2, lines 4-9, Bahl et al '160 teaches that a chemical is coated on the pad such that there is a color change when sufficient amount of fluid has been taken up by the pad.

Therefore, Applicants' claimed invention remains to be deemed obvious over Bahl et al '160.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is (703) 305-7360. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-5408.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

LIC *SIC*

May 4, 2001

Bill Warden
Bill Warden
Supervisory Patent Examiner
Technology Center 1700